PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference KP/PG5023	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/12402	International filing date *(day/month/year)* 03.11.2003	Priority date *(day/month/year)* 05.11.2002
International Patent Classification (IPC) or both national classification and IPC C07K14/16		
Applicant GLAXO GROUP LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07.05.2004	04.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Stoyanov, B Telephone No. +49 89 2399-7726

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/12402

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-52	as originally filed

Claims, Numbers

2-35	as originally filed
1	received on 17.01.2005 with letter of 13.01.2005

Claims, Pages

54-57	as originally filed
53	received on 17.01.2005 with letter of 13.01.2005

Drawings, Sheets

1/53-53/53	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☒ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☒ furnished subsequently to this Authority in written form.

   ☒ furnished subsequently to this Authority in computer readable form.

   ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 32

because:

☒ the said international application, or the said claims Nos. 32 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-31, 33-35
	No:	Claims	-
Inventive step (IS)	Yes:	Claims	1-31, 33-35
	No:	Claims	-
Industrial applicability (IA)	Yes:	Claims	1-31, 33-35
	No:	Claims	32

2. Citations and explanations

see separate sheet

1. Section III
Claim 32 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

2. Section V

2.1 Due to unclear and technically undefined terms and expressions like "**fragment**" and "**immunogenic derivative**" present claims appear to cover subject matter for which no technical support is provided in the meaning of Article 5/6 PCT. This is so, because by doing enough mutations, for instance, any protein immunogenic fragment can be **derived** from any other such fragment. It follows that claims containing such expressions, or claims referring to claims containing such expressions cannot be deemed novel. Consequently, with respect to the issues of novelty and inventive step this IPER has been restricted to those parts of the claims, which appear to be clear, supported and sufficiently disclosed, namely to those parts characterised in examples 1-7.

2.2 For the sake of completeness, the following remarks concerning clarity of claims are also given:

2.4 In the absence of a reference to a particular SEQ ID NO. the abbreviations in claims 14 and 20 are only internal designations and render said claims unclear (Article 6 PCT).

2.5 The subject matter of present claim 16 is unclear, since the expression "exon 1" is not defined by any technical feature.

2.6 The subject matter of present claim 24 is completely unclear since the expression "Pan 9, 5, 6 or 7" has no meaning for the skilled person.

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CLAIMS

1. A polynucleotide which comprises a sequence encoding an HIV envelope protein or HIV envelope protein fragment containing at least one HIV epitope, or immunogenic derivative thereof, which is substantially non-glycosylated when expressed in a mammalian target cell, operably linked to a heterologous promoter, wherein the HIV envelope protein or fragment or immunogenic derivative encoding sequence is adapted to reduce or prevent glycosylation in a mammalian target cell.

2. The polynucleotide according to claim 1 wherein the HIV envelope protein or fragment or immunogenic derivative thereof is gp120 or a fragment or immunogenic derivative thereof.

3. The polynucleotide according to claim 1 or claim 2 wherein the envelope protein lacks a functional secretion signal.

4. The polynucleotide according to claim 2 or claim 3 wherein the gp120 is expressed as a fusion protein comprising at least one other HIV protein or fragment or immunogenic derivative thereof.

5. The polynucleotide according to claim 4 wherein the at least one other HIV protein or fragment or immunogenic derivative is selected from Nef, Gag, RT or Tat.

6. The polynucleotide according to claim 5 wherein the gp120 encoding sequence is linked to a sequence encoding HIV RT or a fragment or immunogenic derivative thereof and a sequence encoding HIV Gag or a fragment or immunogenic derivative thereof and a sequence encoding HIV Nef or a fragment or immunogenic derivative thereof to encode a gp120, RT, Gag and Nef-containing fusion protein.

7. The polynucleotide according to claim 6 wherein the fusion is selected from gp120-RT-Nef-Gag and RT-Nef-Gag-gp120.